United States Food and Drug Administration

Premarket Notification of Devices 501(k)

OMB Control No. 0910-0120 -- EXTENSION

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection helps support implementation of statutory provisions that govern premarket clearance of devices. Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and implementing regulations in 21 CFR part 807 subpart E (§§ 807.81 through 807.100), establish premarket notification procedures. Persons who intend to market a medical device, for which a Premarket Approval application (PMA) is not required, must submit a premarket notification to the Food and Drug Administration (FDA), unless the device is exempt from 510(k) requirements and does not exceed the limitations of exemptions of the device classification regulations, at least 90 days before proposing to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use. Based on the information provided in the notification, FDA must determine whether the new device is substantially equivalent to a legally marketed device. If a device is determined to be not substantially equivalent to a legally marketed device, it must have an approved premarket approval application (PMA), Product Development Protocol, Humanitarian Device Exemption (HDE), request for an evaluation of automatic class III designation (De Novo request) or be reclassified into class I or class II before being marketed. The information collection also helps support implementation of section 510(l), which provides for exemption from premarket notification.

In addition, 42 U.S.C. 282(j)(5)(B), section 402(j)(5)(B) of the PHS Act, requires that a certification accompany human drug, biological, and device product submissions made to FDA. Specifically, at the time of submission of an application under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), or under section 351 of the PHS Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), such application or submission must be accompanied by a certification, Form FDA 3674, that all applicable requirements of section 402(j) of the PHS Act have been met. Where available, such certification must include the appropriate National Clinical Trial (NCT) numbers that are assigned upon submission of required information to the NIH databank at https://clinicaltrials.gov/. To assist sponsors/applicants/submitters in understanding the statutory requirements associated with Form FDA 3674, we have provided a guidance available at: *https://www.fda.gov/RegulatoryInformation/Guidances/ucm125335.htm*. This guidance recommends the applications and submissions FDA considers should be accompanied by the certification form, Form FDA 3674. The applications and submissions identified in the guidance are reflected in the burden analysis. FDA last updated this guidance in 2017.

The following instruments are included in the information collection:

- Form FDA 3514 "*CDRH Premarket Review Submission Cover Sheet*"

- Form FDA 3881 "*Indications for Use*"
- eSTAR Program Interactive PDF Form and instructional webpage
- Form FDA 4062 "*Electronic Submission Template and Resource (eSTAR)*" (for non-In Vitro Diagnostic (IVD) 510(k) submissions)
- Form FDA 4078 "*Electronic Submission Template and Resource (eSTAR)*" (for In Vitro Diagnostic (IVD) 510(k) submissions)
- Form FDA 3674 "*Certifications to Accompany Drug, Biological Product, and Medical Device Applications/Submissions*."

The information collection also includes reference to the guidance document "*Electronic Submission Template for Medical Device 510(k) Submissions*" (October 2023), which communicates the information and guided prompts FDA believes will best facilitate the collection and assembly of the necessary elements of a 'complete' submission, as required by regulation or essential to FDA's substantive review of the 510(k) submission. Likewise, the guidance document "*Recognition and Withdrawal of Voluntary Consensus Standards*," (September 2020), communicates procedures followed by the Center for Devices and Radiological Health (CDRH) when requests for recognition of a voluntary consensus standard for medical products are received. The guidance outlines principles for recognizing a standard wholly, partly, or not at all, as well as reasons and rationales for withdrawing a standard. Section 514 of the FD&C Act (21 U.S.C. 360d) allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions including premarket notifications or other requirements. We publish and update the list of recognized standards regularly at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm. As instructed in the guidance document, any interested party may submit a request for recognition of a standard by mail directed to the CDRH Standards Program (i.e., paper copy) or electronically via email to: CDRHStandardsStaff@fda.hhs.gov.

The information collection also includes the guidance document entitled, "Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics" (April 2018). The guidance describes how publicly accessible databases of human genetic variants can serve as sources of valid scientific evidence to support the clinical validity of genotype-phenotype relationships in FDA's regulatory review of next generation sequencing (NGS)-based tests, as well as single-gene and panel tests based on other technologies. Publicly accessible genetic variant databases may be used to support the clinical validity of NGS-based tests as well as single-gene and panel tests that use other technologies. The guidance also describes FDA's considerations in determining whether a genetic variant database is a source of valid scientific evidence and outlines the voluntary process by which database administrators may apply for FDA recognition. In addition, the guidance recommends that recognized database administrators make information regarding their policies, procedures, and conflicts of interest publicly available on the database's website.

This information collection also includes activities associated with section 520(b) of the FD&C Act (21 U.S.C. 360j(b), governing custom devices. Regulations in 21 CFR 812.3 define a custom device and implementing regulations in 21 CFR part 807.85 provide for exemption from premarket notification. Section 520(b) also provides for the issuance of guidance. The guidance document entitled, "*Custom Device Exemption*" (September 2014), and available for download at

https://www.fda.gov/media/89897/download, explains how FDA interprets provisions in section 520(b)(2)(B) of the FD&C Act; describes what information should be submitted in a Custom Device Annual Report ("*annual report*"); and provides recommendations on how to submit an annual report for devices distributed under the custom device exemption.

Finally, we discuss the guidance document entitled, "*Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the COVID-19 Public Health Emergency*," announced in the *Federal Register* of March 27, 2023 (88 FR 18153), which describes a phased approach intended to help avoid disruption in device supply and help facilitate compliance with applicable legal requirements. The recommendations discussed in the guidance document result in the one-time collection of information intended to ensure an orderly and transparent transition from temporary policies established during the COVID-19 public health emergency to normal operations. Because the information collection recommendations apply to specific medical devices already in distribution, we believe the information discussed is appropriately characterized as nonstandardized follow-up designed to clarify responses to approved collections of information, i.e., plans for compliance with applicable requirements unique to that distributed device. We therefore believe the activity constitutes the collection of non-identical and/or follow-up information, as defined under 5 CFR 1320.3. At the same time, we expect some degree of fluctuation in future submissions under 21 CFR 807 subpart E, as a result of implementation of the medical device transition plan.

Accordingly, we are requesting OMB approval for the information collection activities included in the applicable regulations, and the guidance documents and agency forms discussed and identified in this supporting statement.

2. Purpose and Use of the Information Collection

FDA is mandated under the FD&C Act to make the final decision of whether a device is substantially equivalent or not substantially equivalent to a legally marketed device. The premarket notification review process allows for scientific and/or medical review of devices, subject to 510(k) of the FD&C Act, to confirm that the new devices are as safe and as effective as legally marketed predicate devices. This review process, therefore, prevents potentially unsafe and/or ineffective devices, including those with fraudulent claims, from entering the U.S. market.

Additionally, we utilize submission instruments such as forms, eSTAR, and other web-based process enhancement tools to better focus limited agency resources on reviewing submissions. We also encourage medical device sponsors to use FDA-recognized voluntary consensus standards in submissions, as conformity to relevant standards helps streamline regulatory review, foster quality, and may facilitate a manufacturer's preparation of a 510(k) submission. FDA also uses information submitted in support of publicly accessible human genetic variant databases to evaluate whether such databases may serve as sources of valid scientific evidence supporting the clinical validity of genotype-phenotype relationships in applicable premarket submissions. This information is used to evaluate requests for database recognition and periodically reevaluate recognized databases, helping ensure that information used to support clinical validity is reliable, transparent, and appropriate for use in premarket review.

The collection of information required under 42 U.S.C. 282(j)(5)(B), section 402(j)(5)(B) of the PHS Act, can be submitted electronically or manually to FDA. This information will be submitted to FDA with new investigational and marketing applications/submissions and certain additional submissions to such applications for human drugs, biological products, and devices. The

information is used by FDA to confirm that sponsors/applicants/submitters have complied with the certification provisions in the law with regard to any applicable clinical trials referenced in the investigational or marketing applications/submissions with which the certification is submitted. The information also provides a means of correlating the clinical trials contained in the applications/submissions to FDA with the information contained in the ClinicalTrials.gov data bank.
Respondents to the information collection are from private sector businesses or other for-profit organizations.

3. Use of Improved Information Technology and Burden Reduction

Respondents can make single submissions in an electronic format such as eCopies and eSubmissions, submissions created using an electronic submission template (e.g., "electronic Submission Template and Resource" (eSTAR)). Consistent with our authority in section 745A(b) of the FD&C Act (21 U.S.C. 379k-1(b)), and performance goals found in our Medical Device User Fee Amendments (MDUFA) IV Commitment Letter, we developed eSTAR for use with the Center for Devices and Radiological Health Customer Collaboration Portal. We use eSTAR as a tool to facilitate the preparation of submissions in electronic format (available on FDA's website at https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-programand identified as Form FDA 4062 "Electronic Submission Template and Resource (eSTAR)" (for Non-In Vitro Diagnostic submissions) and form FDA 4078 "Electronic Submission Template and Resource (eSTAR)" (for In Vitro Diagnostic submissions)). We believe respondents' use of eSTAR will significantly reduce burden attendant to application submissions by providing a uniform format for requisite elements and by enhancing user interface through the use of modernized technology. We continue to make process improvements and technological enhancements consistent with our MDUFA V Commitment letter found at https://www.fda.gov/media/157074/download (included in OMB control number 0910-0511). We estimate 99% of the respondents will use electronic means to fulfill the information collection.

The Agency is not yet equipped to receive all investigational and marketing applications/submissions electronically; therefore, this reporting requirement will not mandate the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology for the certification required by section 402(j)(5)(B) of the PHS Act. However, FDA developed Form FDA 3674 to assist respondents with submitting this certification to the Agency. This form is designed to be able to be electronically completed and, if desired, electronically submitted by the applicant/submitter. Because the form will accompany an investigational or marketing application/submission, the form will be submitted in the same manner as the application/submission that it accompanies. There are Center-wide efforts to moving to e-submission of applications, and we have worked very closely with those efforts and have updated the certification form so that it allows for the use of additional continuation pages, drop down menus, and electronic signatures. We believe these efforts increase the usability of the certification form and make submission easier for the end user. FDA estimates that 80% of respondents will use electronic means to fulfill the agency's information collection.

Information associated with publicly accessible human genetic variant databases that is included in this information collection is also expected to be submitted electronically, consistent with FDA's use of electronic submission processes for medical device premarket review.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Upon evaluation of our inventory, we note related information collection activity associated with registration and listing requirements in 21 CFR part 807 subparts A through D. In this information collection we are specifically covering premarket notifications required in 21 CFR part 807 subpart E.

In addition, only the submitter of the medical product application/submission has the ability to certify that the requirements of 42 U.S.C. § 282(j), section 402(j) PHS Act have been met or are not applicable to the clinical trials being referenced in the application/ submission being submitted to FDA. This information is not otherwise available to FDA. Such information is only available from the individuals or entities responsible for submitting such information to the ClinicalTrials.gov data bank, or from the product applicants/submitters and product application/submission holders referenced in their applications/submissions. The information will vary for each drug, biological product, or device application/ 3 submission.

5. Impact on Small Businesses or Other Small Entities

We do not believe the information collection imposes undue burden on small entities. Respondents to the information collection submit user fees in conjunction with FDA review of premarket notification of medical devices. Under statutory provisions, small businesses may qualify for reduced fees.

6. Consequences of Collecting the Information Less Frequently

The information collection is consistent with applicable statutory and regulatory requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the *Federal Register* of March19, 2026 (91 FR 13310), we published a 60-day notice. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3514 (CDRH Premarket Review Cover Sheet), Form FDA 4062 "Electronic Submission Template and Resource (eSTAR)" (for non-In Vitro Diagnostic (IVD) 510(k) submissions), Form FDA 4078 "Electronic Submission Template and Resource (eSTAR)" (for In Vitro Diagnostic (IVD) 510(k)

submissions), and Form FDA 3674 Certification of Compliance is contact name, work telephone number, work email address, work address, and work fax number. Form FDA 3881 (Indications for Use) is used for this collection, but no PII is collected on this form. We have determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, (See 21 CFR 20), consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table. 1—Estimated Annual Reporting Burden

Activity and 21 CFR Part/ Section	Form Number	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
21 CFR Part 807, Subpart E, PREMARKET NOTIFICATION PROCEDURES						
510(k) submission (807 subpart E)	FDA 3881	3,800	1	3,800	79.25	301,150
Summary cover sheet (807.87)	FDA 3514	1,906	1	1,906	0.5	953
Status request (807.90(a)(3))		1	1	1	0.25	1
510(k) summary (807.92)		2,742	1	2,742	4	10,968
510(k) statement (807.93)		130	1	130	.08 (5 minutes)	10
510(k) submission (807 subpart E)—using eSTAR format	FDA 4062, FDA 4078	3,800	1	3,800	40	152,000
Guidance Document Recommendations:						
Request for recognition of a voluntary consensus standard		5	1	5	1	5
Annual reporting for custom devices under 520(b) of the FD&C Act		31	1	31	40	1,240
42 CFR part 11, Clinical Trials Registration and Results Information Submission, subparts D and E; and FDA Guidance "Form FDA 3674--Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions"						
Certification to accompany 510(k) submissions	FDA 3674	3,800	1	3,800	0.75 (45 minutes)	2,850
Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics						
Application for recognition of genetic database		5	1	5	80	400
Electronic Submission Template and Resource (eSTAR)						
eSTAR setup—one-time burden		80	1	80	0.08 (5 minutes)	6
TOTAL				16,295		469,583

Table. 2—Estimated Annual Recordkeeping Burden

Activity and 21 CFR Part/ Section	Form Number	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics						
Maintenance of recognition activities		5	1	5	20	100

Table. 3—Estimated Annual Third-Party Disclosure Burden

Activity and 21 CFR Part/ Section	Form Number	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics						
Public disclosure of policies, procedures, and conflicts of interest		5	1	5	1	5

The regulations in 21 CFR 807 subpart E and the associated guidance documents prescribe specific format and content elements necessary for FDA action on submissions. Based on recent trends, an estimated 3,800 submissions are expected each year. Our administrative and technical staff, who are familiar with the requirements for submission of premarket notifications, estimate that it takes an average of 79.25 hours to prepare a submission. Because the PRA defines a recordkeeping requirement to include reporting those records to the Federal government (5 CFR 1320.3(m)), we account for burden associated with preparing, transmitting, and responding to follow-up requests from FDA for supplemental information in our estimate. We expect to receive approximately 3,800 510(k) submissions via eSTAR per year. We estimate that eSTAR submissions require 40 hours per submission. Based on a recent review of the summary cover sheet, we estimate 1,906 summary cover sheets will be received annually. We assume 30 minutes are needed to complete the summary cover sheet. Based on market trends, FDA estimates that 5 respondents will submit information pertaining to a request for recognition of a voluntary standard and that the activity requires an average of 1 hour. We estimate a one-time setup burden of 5 minutes for approximately 80 new eSTAR users annually.

Transparency and Public Accessibility: FDA recommends that genetic variant database administrators make publicly available sufficient information regarding data sources and standard operating procedures (SOPs) for evaluation of evidence to allow FDA and the public to understand the criteria and processes used to collect and evaluate evidence about variants and enable patients and healthcare providers to make fully informed medical decisions.

Data Preservation: FDA recommends that genetic variant database administrators have processes in place for assessing overall database stability and architecture and for ensuring that data linkages are properly maintained. When a genetic variant database contains linkages to secondary databases, the genetic variant database administrator should have predefined processes in place to recognize changes to the secondary databases and account for them in version control of the primary database. FDA recommends genetic variant database administrators back-up the database on a regular basis so that it can be reinstated as necessary.

Genetic variant database administrators should have a plan in place to ensure database content and processes are preserved in the event a genetic variant database ceases operations permanently or temporarily (e.g., a database loses funding, infrastructure upgrades). A location to deposit data, including versioning information and supporting SOPs and documentation, in the event that the genetic variant database ceases operation should be identified.

To the extent possible or applicable, database administrators are required to submit metadata. This metadata should include information about the analytical performance of the test used to detect the variant, including the number of independent laboratories and/or studies reporting the variant,

name of the laboratory(ies) that reported the variant, the name of the test used to detect the variant, and details of the technical characteristics of the test that was used (e.g., reference sequence version or build, instrument, software, bioinformatics tools, etc.). For germline variants, metadata should also include, to the extent possible, variant characteristics (which could include but is not limited to, patient ethnicity, zygosity, phasing, and segregation). For somatic variants, metadata should include, to the extent possible, additional information about the context in which the variant was detected (which could include but is not limited to, variant allele frequency, tumor only versus tumor-normal matched sequencing, cellularity). For cases in which multiple genetic variants factor into determining the overall risk of developing a disease or condition, database administrators should include any multivariant or polygenic scoring methods used in the metadata. As applicable, database administrators should also include as much information as is available regarding the contribution of environmental exposures to the development of a genotype-associated disease or condition. Genetic variant databases should clearly and transparently document evidence source(s) used to support variant assertions (e.g., literature, well-documented case histories). We believe databases administrators should make an effort to ensure no duplication within reason.

The following estimates are based on FDA's experience with Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostic Guidance FDA expects no more than 5 submissions for database recognition per year. Respondents are administrators of genetic databases. Our estimate of five respondents per year is based on the current number of databases that may meet FDA recommendations for recognition and seek such recognition.

Based on our experience and the nature of the information, we estimate that it will take an average of 80 hours to complete and submit an application for recognition. We estimate that maintenance of recognition activities will take approximately one-fourth of that time (20 hours) annually. We estimate that it will take approximately 1 hour to post the information on the website.

12b. Annualized Cost Burden Estimate

Assuming that activities identified in *12a* are performed by labor categories consistent with that of "*Lawyer*" (occupation code 23-1011) as defined by the Bureau of Labor Statistics (BLS), we use a mean hourly wage rate of $87.86/hour for a lawyer consistent with 2024 data for our calculations.[1] We factor this figure by two to account for benefits and overhead ($175.72.), multiply the total by the annual burden hours and estimate annual respondent costs to be $73,886,939 (rounded) [$157.48 x 469,183 hours].

The estimated annual cost for a company to pay an employee to respond to the information collection is based on the average hourly salary of a database administrator multiplied by the total burden hours. The mean hourly wage cost is $59.18 per hour for Database Administrators and Architects (occupation code 15-1245), based on the "May 2024 National Occupational Employment and Wage Estimates United States" that is available at https://www.bls.gov/oes/current/oes_nat.htm#15-0000. We estimate that the average annualized burden cost for respondents is approximately $23,336 (rounded).

[1] http://www.bls.gov/oes/current/oes_nat.htm, accessed 5/1/23.

Respondent Labor Category	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Lawyer	469,183	$175.72	$82,444,83759
Database administrators	505	$118.36	$59,772
Total			$82,504,609

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We estimate 251 full time equivalent (FTE) positions consisting of a combination of medical officers, dental officers, scientific, and engineering professionals and support staff are allocated to the administration of the information collection. Based on an internal cost model, we assume a fully-loaded cost of $362,272 per position. We calculate annual Federal costs to be $90,930,272.

15. Explanation for Program Changes or Adjustments*

Our estimated burden for the information collection reflects an overall increase of 146,309 hours and an increase of 3,630 responses. A significant driver of the overall burden increase is the growth in 510(k) submissions, which has risen from approximately 100 to 3,800 submissions annually.

This submission corrects the burden inventory to reflect burden changes that were previously approved but were inadvertently not carried forward during the 2023 non-substantive change request that consolidated OMB Control No. 0910-0850 into this information collection. Specifically, this submission incorporates the burden previously approved under OMB Control No. 0910-0850. In addition, we have made nominal adjustments to individual provisions to reflect expected fluctuations in submission volumes.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB control number, its expiration date, and an explanation of its significance will be displayed with the information collection as required by 5 CFR 1320.5. Consistent with established practice, FDA publishes a *Federal Register* notice announcing OMB approval of the information collection associated with its guidance documents and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.